PATENT
ATTY. DOCKET NO. MMI1130-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Ferrie et al.	Art Unit:	1634
Application No.:	10/754,437	Examiner:	Jeanine Anne Goldberg
Filed:	January 9, 2004	Conf. No.	8712
Title:	COMPOSITIONS AND METHODS FOR DETERMINING CANINE GENDER		

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF APPLICANTS UNDER 37 C.F.R. §1.132

Sir:

We, Sue DeNise and Bonita J.M. Ferrie, two of the co-inventors of the above-identified application, do hereby declare and state that:

1. We are familiar with the content of the above-identified application, including the discovery of methods and primers for determining the gender of a subject from the canis familiaris species. In particular, we are familiar with the number and kind of dog breeds used and the number of male and female dogs sampled to generate the data used in the above application.

2. We are familiar and were instrumental in generating the data as present in Exhibit C. Research was conducted, *inter alia*, to further test the robustness of the assay using methods and primers as described in the above application. The Exhibit shows the number of dogs (125,037) and breeds used (231) in the analysis. From this analysis the error call rate; i.e., where the gender genotyped is opposite of that reported by the owner, was determined to be 1.6% (i.e., 1,996/125,037). Further, there were no database errors detected (i.e., no single allele in females was detected where that allele corresponded to "Y" instead of "X"). This data provides further

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support for the teachings of the above application, where using the methods and primers as disclosed accurately and precisely determines gender in a wide range of breeds.

3. Further, in a study conducted with 74 dog samples (34 female and 40 males), using the assay methods and primers as described in the above application, where the assay results in a single PCR product of approximately 140 bases in females (corresponding to the X chromosome) and two PCR products of approximately 140 bases and 142 bases in males (corresponding to the Y chromosome), gender was determined correctly in 100% of the samples. This observation further supports the teachings of the above application in that the results are consistent across male and female samples.

4. Moreover, these results corroborate the disclosure at paragraphs [0030], [0070], [0075], and [0100]-[0107], as well as Figures 1-4, in the above application as filed.

5. We further declare that all statements made herein of knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

January 25, 2006
Date

Sue DeNise

January 25, 2006
Date

Bonita J.M. Ferrie

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